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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,217	11/04/2003	Brenda F. Baker	ISIS-5319	5185
27180	7590	11/15/2005	EXAMINER	
ISIS PHARMACEUTICALS INC 1896 RUTHERFORD RD. CARLSBAD, CA 92008			BOWMAN, AMY HUDSON	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/701,217

Applicant(s)

BAKER ET AL.

Examiner

Amy H. Bowman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2-10, 17, 18 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more specifically a peptide nucleic acid of the formula shown in claim 18, classified in class 435, subclass 6.
- II. Claims 1, 2-10, 17, 19 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more specifically a peptide nucleic acid of the formula shown in claim 19, classified in class 435, subclass 6.
- III. Claims 1, 2-10, 17, 20, 21 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more specifically a peptide nucleic acid of the formula shown in claim 20, classified in class 435, subclass 6.
- IV. Claims 1, 2-10, 17, 22 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more

specifically a peptide nucleic acid of the formula shown in claim 22,  
classified in class 435, subclass 6.

- V. Claims 1, 2-10, 17, 23 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more specifically a peptide nucleic acid of the formula shown in claim 23, classified in class 435, subclass 6.
- VI. Claims 1, 2-10, 17, 24 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more specifically a peptide nucleic acid of the formula shown in claim 24, classified in class 435, subclass 6.
- VII. Claims 1, 2-10, 17, 25 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more specifically a peptide nucleic acid of the formula shown in claim 25, classified in class 435, subclass 6.
- VIII. Claims 1, 2-10, 17, 26 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid modification, more specifically a peptide nucleic acid of the formula shown in claim 26, classified in class 435, subclass 6.

- IX. Claims 1, 2-10, 27 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a peptide nucleic acid mimic modification, more specifically the modification shown in claim 27, classified in class 435, subclass 6.
- X. Claims 1, 2-16, and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a morpholino nucleic acid modification, classified in class 435, subclass 6.
- XI. Claims 1, 2-10, 28 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a hexose sugar with amide linkage modification, more specifically the modification shown in claim 28, classified in class 435, subclass 6.
- XII. Claims 1, 2-10, 29 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at least one nucleotide having a cyclohexenyl nucleic acid modification, more specifically the modification shown in claim 29, classified in class 435, subclass 6.
- XIII. Claims 1, 2-10, 30, 31 and 67, drawn to a composition comprising a first and a second oligomer wherein at least one of the oligomers includes at

least one nucleotide having an acyclic backbone moiety, more specifically the modification shown in claim 30, classified in class 435, subclass 6.

- XIV. Claims 32-39, 46, 47 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 47, classified in class 435, subclass 6.
- XV. Claims 32-39, 46, 48 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 48, classified in class 435, subclass 6.
- XVI. Claims 32-39, 46, 49, 50 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 49, classified in class 435, subclass 6.
- XVII. Claims 32-39, 46, 51 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic

acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 51, classified in class 435, subclass 6.

XVIII. Claims 32-39, 46, 52 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 52, classified in class 435, subclass 6.

XIX. Claims 32-39, 46, 53 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 53, classified in class 435, subclass 6.

XX. Claims 32-39, 46, 54 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 54, classified in class 435, subclass 6.

- XXI. Claims 32-39, 46, 55 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid modification, more specifically the modification shown in claim 55, classified in class 435, subclass 6.
- XXII. Claims 32-39, 56 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a peptide nucleic acid mimic modification, more specifically the modification shown in claim 56, classified in class 435, subclass 6.
- XXIII. Claims 32-45 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a morpholino nucleic acid modification, classified in class 435, subclass 6.
- XXIV. Claims 32-39, 57 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a hexose



sugar with amide linkage modification, more specifically the modification shown in claim 57, classified in class 435, subclass 6.

- XXV. Claims 32-39, 58 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having a cyclohexenyl nucleic acid modification, more specifically the modification shown in claim 58, classified in class 435, subclass 6.
- XXVI. Claims 32-39, 59, 60 and 68, drawn to a composition comprising an oligomer complementary to and capable of hybridizing to a target nucleic acid and at least one protein, said protein comprising at least a portion of RISC, wherein said oligomer comprises at least one nucleotide having an acyclic backbone moiety, more specifically the modification shown in claim 59, classified in class 435, subclass 6.
- XXVII. Claims 61-66 and 69, drawn to an oligomer having at least a first and a second region, wherein said oligomer further includes at least one nucleotide having a peptide nucleic acid modification, classified in class 435, subclass 6.
- XXVIII. Claims 61-66 and 69, drawn to an oligomer having at least a first and a second region, wherein said oligomer further includes at least one nucleotide having a peptide nucleic acid mimic modification, classified in class 435, subclass 6.

- XXIX. Claims 61-66 and 69, drawn to an oligomer having at least a first and a second region, wherein said oligomer further includes at least one nucleotide having a morpholino nucleic acid modification, classified in class 435, subclass 6.
- XXX. Claims 61-66 and 69, drawn to an oligomer having at least a first and a second region, wherein said oligomer further includes at least one nucleotide having an acyclic backbone moiety, classified in class 435, subclass 6.
- XXXI. Claims 70 and 73, drawn to a method of modulating expression of a target nucleic acid in a cell comprising contacting said cell with a composition of groups I-XIII, respectively, and to a method of treating or preventing a disease or disorder associated with a target nucleic acid comprising administering the compound, classified in class 514, subclass 44. **Upon election of this group, a further election is required of a specific compound of groups I-XIII, as each is patentably distinct.**
- XXXII. Claims 71 and 74, drawn to a method of modulating expression of a target nucleic acid in a cell comprising contacting said cell with a composition of groups XIV-XXVI, respectively, and to a method of treating or preventing a disease or disorder associated with a target nucleic acid comprising administering the compound, classified in class 514, subclass 44. **Upon election of this group, a further election is required of a specific compound of groups XIV-XXVI, as each is patentably distinct.**

XXXIII. Claims 72 and 75, drawn to a method of modulating expression of a target nucleic acid in a cell comprising contacting said cell with a composition of groups XXVII-XXX, respectively, and to a method of treating or preventing a disease or disorder associated with a target nucleic acid comprising administering the compound, classified in class 514, subclass 44. **Upon election of this group, a further election is required of a specific compound of groups XXVII-XXX, as each is patentably distinct.**

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-VIII are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I-VIII have not been disclosed as capable of use together and have different effects. Each of the inventions is drawn to a separate and distinct structure, each requiring a separate search and examination. Each of the structures are considered patentably distinct inventions and do not contain a common structural core. To search for any one of the PNA structures would not necessarily return art for any other of the PNA structures. Each of the structures would function based on their distinct structure. Therefore, to search more than one of the instantly claimed structures presents a search burden.

The inventions of groups I-XIII are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I-XIII have not been disclosed as capable of use together and have different effects. The PNA inventions of groups I-VIII are separate and distinct for the reasons explained above. Further, each of the inventions of groups I-XIII is drawn to separate and distinct structures, each requiring a separate search and examination. Each of the structures are considered patentably distinct inventions and do not contain a common structural core. Specifically, groups I-VIII are drawn to various PNA structures, whereas group IX is drawn to a peptide nucleic acid mimic structure, group X is drawn to a morpholino structure, group XI is drawn to a hexose sugar with amide linkage structure, group XII is drawn to a cyclohexenyl structure, and group XIII is drawn to an acyclic structure. Each of these structures are separate and distinct, each resulting in a unique search. To search for any one of the above structures would not necessarily return art for any other of the unique structures. Each of the compounds would function based on their distinct structure. Therefore, to search more than one of the instantly claimed structures presents a search burden.

The inventions of groups XIV-XXI are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups XIV-XXI have not been

disclosed as capable of use together and have different effects. Each of the inventions is drawn to a separate and distinct structure, each requiring a separate search and examination. Each of the structures are considered patentably distinct inventions and do not contain a common structural core. To search for any one of the PNA structures would not necessarily return art for any other of the PNA structures. Each of the structures would function based on their distinct structure. Therefore, to search more than one of the instantly claimed structures presents a search burden.

The inventions of groups XIV-XXVI are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups XIV-XXVI have not been disclosed as capable of use together and have different effects. The PNA inventions of groups XIV-XXI are separate and distinct for the reasons explained above. Further, each of the inventions of groups XIV-XXVI is drawn to separate and distinct structures, each requiring a separate search and examination. Each of the structures are considered patentably distinct inventions and do not contain a common structural core. Specifically, groups XIV-XXI are drawn to various PNA structures, whereas group XXII is drawn to a peptide nucleic acid mimic structure, group XXIII is drawn to a morpholino structure, group XXIV is drawn to a hexose sugar with amide linkage structure, group XXV is drawn to a cyclohexenyl structure, and group XXVI is drawn to an acyclic structure. Each of these structures are separate and distinct, each resulting in a unique search. To search for any one of the above structures would not necessarily return art

for any other of the unique structures. Each of the compounds would function based on their distinct structure. Therefore, to search more than one of the instantly claimed structures presents a search burden.

The inventions of groups I-XIII are each unrelated to the inventions of groups XIV-XXVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I-XIII have not been disclosed as capable of use together and have different effects than the inventions of groups XIV-XXVI. The inventions of groups I-XIII do not have the same structural requirements as the inventions of groups XIV-XXVI. Specifically, the inventions of groups XIV-XXVI have a limitation wherein the oligomer is capable of hybridizing to a selected target nucleic acid and at least one protein, said protein comprising at least a portion of RISC. This is not a consideration of groups I-XIII. Additionally, groups XIV-XXVI encompass structures that may be single stranded, whereas the inventions of groups I-XIII are limited to compositions comprising a first and a second oligomer. Each of the structures are considered patentably distinct inventions and do not contain a common structural core. To search for any one of the compositions of groups I-XIII would not necessarily return art for any of the compositions of groups XIV-XXVI. Each of the compounds would function based on their distinct structure. Therefore, to search more than one of the instantly claimed structures presents a search burden.

The inventions of groups XXVII-XXX are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups XXVII-XXX have not been disclosed as capable of use together and have different effects. Each of the inventions of groups XXVII-XXX is drawn to separate and distinct structures, each requiring a separate search and examination. Each of the structures are considered patentably distinct inventions and do not contain a common structural core. Specifically, group XXVII is drawn to an oligomer comprising a PNA structure, whereas group XXVIII is drawn to an oligomer comprising a peptide nucleic acid mimic structure, group XXIX is drawn to an oligomer comprising a morpholino structure, and group XXX is drawn to an oligomer comprising an acyclic structure. Each of these structures are separate and distinct, each resulting in a unique search. To search for any one of the above structures would not necessarily return art for any other of the unique structures. Each of the compounds would function based on their distinct structure. Therefore, to search more than one of the instantly claimed structures presents a search burden.

The inventions of groups I-XXVI are each unrelated to the inventions of groups XXVII-XXX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I-XXVI have not been disclosed as capable of use together and have different effects than the inventions of groups XXVII-XXX. The inventions of groups I-XXVI do

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not have the same structural requirements as the inventions of groups XXVII-XXX.

Specifically, the inventions of groups I-XIII are drawn to compositions comprising first and second oligomers with various modifications, whereas the inventions of groups XIV-XXVI have a limitation wherein the oligomer is capable of hybridizing to a selected target nucleic acid and at least one protein, said protein comprising at least a portion of RISC. The inventions of groups XXVII-XXX are drawn to an oligomer with a first and second regions capable of hybridizing to each other. The inventions of groups XXVII-XXX encompass hairpin structures, which is not a consideration of groups I-XXVI.

Each of the structures are considered patentably distinct inventions and do not contain a common structural core. To search for any one of the compositions of groups I-XXVI would not necessarily return art for any of the oligomers of groups XXVII-XXX. Each of the compounds would function based on their distinct structure. Therefore, to search more than one of the instantly claimed structures presents a search burden.

The inventions of groups I-XIII are related to the invention of group XXXI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of group XXXI can be practiced with another materially different product, such as an antisense oligonucleotide or a ribozyme, which does not involve the oligomers of groups I-XIII. To search for any one of the compositions of



groups I-XIII would not necessarily return art for the process of group XXXI. Therefore, to search more than one of the instantly claimed inventions presents a search burden.

The inventions of groups XIV-XXX are each unrelated to the invention of group XXXI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups XIV-XXX have not been disclosed as capable of use together and have different effects than the invention of group XXXI. Specifically, the inventions of groups XIV-XXX are drawn to compounds that are not an element of the method of group XXXI. The method of group XXXI comprises distinct steps that do not utilize any of the compounds of groups XIV-XXX. To search for the method of group XXXI would not necessarily return art for any of the unrelated compounds of groups XIV-XXX. Therefore, to search more than one of the instantly claimed inventions presents a search burden.

The inventions of groups XIV-XXVI are related to the invention of group XXXII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of group XXXII can be practiced with another materially different product, such as an antisense oligonucleotide or a ribozyme, which does not involve the oligomers of groups XIV-XXVI. To search for any one of the compositions of groups XIV-XXVI would not necessarily return art for the process of group XXXII.

Therefore, to search more than one of the instantly claimed inventions presents a search burden.

The inventions of groups I-XIII and XXVII-XXX are each unrelated to the invention of group XXXII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I-XIII and XXVII-XXX have not been disclosed as capable of use together and have different effects than the invention of group XXXII.

Specifically, the inventions of groups I-XIII and XXVII-XXX are drawn to compounds that are not an element of the method of group XXXII. The method of group XXXII comprises distinct steps that do not utilize any of the compounds of groups I-XIII and XXVII-XXX. To search for the method of group XXXII would not necessarily return art for any of the unrelated compounds of groups I-XIII and XXVII-XXX. Therefore, to search more than one of the instantly claimed inventions presents a search burden.

The inventions of groups XXVII-XXX are related to the invention of group XXXIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of group XXXIII can be practiced with another materially different product, such as an antisense oligonucleotide or a ribozyme, which does not involve the oligomers of groups XXVII-XXX. To search for any one of the compositions

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of groups XXVII-XXX would not necessarily return art for the process of group XXXIII. Therefore, to search more than one of the instantly claimed inventions presents a search burden.

The inventions of groups I-XXVI are each unrelated to the invention of group XXXIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I-XXVI have not been disclosed as capable of use together and have different effects than the invention of group XXXIII. Specifically, the inventions of groups I-XXVI are drawn to compounds that are not an element of the method of group XXXIII. The method of group XXXIII comprises distinct steps that do not utilize any of the compounds of groups I-XXVI. To search for the method of group XXXIII would not necessarily return art for any of the unrelated compounds of groups I-XXVI. Therefore, to search more than one of the instantly claimed inventions presents a search burden.

The inventions of groups XXXI-XXXIII are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups XXXI-XXXIII have not been disclosed as capable of use together and have different effects. Specifically, each of the inventions is drawn to separate and distinct methods, each utilizing separate and distinct compounds. To search for any of the methods of groups XXXI-XXXIII

would not necessarily return art for any of the other methods. Therefore, to search more than one of the instantly claimed inventions presents a search burden.

Because the inventions are distinct for the reasons given above, and because a search for art against one group would not necessarily return art against another, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an

allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman  
Examiner  
Art Unit 1635

  
**J.D. SCHULTZ, Ph.D.**  
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